UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MUTUAL PHARMACEUTICAL COMPANY, INC.,	:		
Plaintiff,	:	Civil Action No.:	03-1116 (RMU)
v.	:	Document No.:	10
PFIZER, INC.,	:		
Defendant.	:		

MEMORANDUM OPINION

GRANTING THE DEFENDANT'S MOTION TO DISMISS

I. INTRODUCTION

This case comes before the court on the defendant's motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(1). Plaintiff Mutual Pharmaceutical Company, a generic drug manufacturer, seeks a declaratory judgment declaring that its product does not infringe the patent of defendant Pfizer, a pioneer drug manufacturer. The defendant alleges that the court does not have subject-matter jurisdiction over the plaintiff's action. Because the plaintiff does not have a reasonable apprehension of an infringement suit, an actual controversy does not exist. Consequently, the court grants the defendant's motion.

II. BACKGROUND

A. Factual Background

1. Statutory and Regulatory Background

The Food and Drug Administration ("FDA") regulates the pharmaceutical industry. The

Federal Food, Drug and Cosmetic Act ("FFDCA") is the statute that governs the manufacture and distribution of drugs and medical devices. 21 U.S.C. §§ 301 *et seq*. Generic drugs are drugs that are sold without a brand name, but contain the same active ingredient as a brand-name pharmaceutical, commonly referred to as the "pioneer" drug. *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998). Ordinarily, a company seeking to market a pioneer drug must complete a New Drug Application ("NDA"). *Id*. Preparing an NDA consists of conducting studies and gathering data that prove the drug's safety and efficacy. *Id*. An NDA is also required to contain a list of any patents that cover the pioneer drug, as well as any patents that cover a specific use for the drug. *Purepac Pharm. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004). The FDA then publishes all patent information that a pharmaceutical company submits regarding a pioneer drug in a publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book." 21 U.S.C. § 355(j)(7)(A).

In 1984, Congress enacted the Hatch-Waxman Amendments ("the Amendments") to the FFDCA, which simplified the process for FDA approval of generic drugs. *Mova Pharm.*, 140 F.3d at 1063. Under the Amendments, applicants who wish to market generic versions of pioneer drugs may file an Abbreviated New Drug Application ("ANDA") which relies on the FDA's previous determination that the pioneer drug is safe and effective. *Id*. Thus, the generic drug manufacturer need not submit new safety and effectiveness studies. *Id*. One requirement of the ANDA is that for each patent applicable to the pioneer drug, the ANDA applicant must certify whether the generic drug would infringe that patent, and if not, the reasons why it would not. *Id*. To satisfy this requirement, an ANDA applicant may certify that (I) the required patent information has not been filed, (II) the patent has expired, (III) the patent has not expired, but

will expire on a particular date, or (IV) that the patent is invalid or will not be infringed by the drug for which the ANDA applicant seeks approval. 21 U.S.C. § 355(j)(2)(A)(vii). If an ANDA applicant makes a certification under clause IV (commonly referred to as a "paragraph IV certification") and the pioneer patent holder brings suit within 45 days, the FDA must delay its approval of the ANDA until the earlier of 30 months or the date of a court decision finding the patent invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iii); *Mova Pharm.*, 140 F.3d at 1064.

The first applicant to file an ANDA containing a paragraph IV certification is known as a "first filer" and is eligible for a 180-day exclusivity period during which the it is entitled to have the sole generic version of the pioneer drug on the market. 21 U.S.C. § 355(j)(5)(B)(iv). This exclusivity period is calculated from the earlier of 1) the date of the first commercial marketing of the generic drug by the first filer, or 2) the date of a court decision declaring the patent at issue invalid or not infringed. 21 U.S.C.§ 355(j)(5)(B)(iv). Any subsequent ANDA filer must wait until the expiration of the first filer's 180-day exclusivity period before receiving FDA approval of its ANDA. *Id*.

2. The Pfizer-Mutual-Teva Interaction

The plaintiff is a generic pharmaceutical manufacturer seeking a declaratory judgment that would establish that its manufacture, use or sale of *quinapril hydrochloride* tablets will not infringe the defendant's patent, United States Patent Number 4,473,450 ("the '450 patent"). Compl. ¶ 14. The defendant manufacturers and markets Accupril® brand *quinapril hydrochloride*, a medication currently approved for the treatment of hypertension and congestive heart failure. Compl. ¶ 5; Pl.'s Opp'n. at 2.

On January 15, 1999, Teva Pharmaceuticals USA, Inc. ("Teva") filed an ANDA seeking

approval to market generic *quinapril hydrochloride* tablets. Def.'s Mot. at 6; Pl.'s Opp'n at 8. Teva's ANDA contained a paragraph IV certification, asserting that the '450 patent was invalid. *Id*. In response, Warner-Lambert Company, the defendant's predecessor-in-interest, filed suit in the United States District Court for the District of New Jersey on March 2, 1999, which was within 45 days of Teva's paragraph IV certification. *Id*. That case is still pending. *Id*. As the first filer, Teva is entitled to the 180-day exclusivity period, which will commence on the date it first commercially markets its generic *quinapril hydrochloride* or the date on which a court declares the '450 patent invalid. 21 U.S.C.§ 355(j)(5)(B)(iv); Def.'s Mot. at 6. To date, neither event has occurred.

On January 30, 2003, the plaintiff submitted an ANDA to the FDA seeking approval to market its own generic *quinapril hydrochloride* tablets. Compl. ¶ 6. As part of its ANDA, the plaintiff also made a paragraph IV certification asserting that its ANDA would not infringe the '450 patent. *Id*. ¶ 7. The defendant has not filed suit against the plaintiff for infringement of the '450 patent within 45 days of the paragraph IV certification. *Id*. ¶ 11.

Because Teva has not begun commercial marketing of its generic *quinapril hydrochloride* tablets and the New Jersey district court has not yet declared the '450 patent invalid or not infringed, the 180-day exclusivity period has not begun to run. If the plaintiff prevails in this case, and the court declares the '450 patent invalid or not infringed, the180-day clock will start running on Teva's exclusivity period, clearing the way for the plaintiff to begin marketing its drug at the expiration of that 180-day period. Pl.'s Opp'n at 7-8 (noting that filing the instant action for declaratory judgment was the "only step it could [take] to clear the way for the FDA to

give final approval to Mutual's ANDA").[1]

3. Procedural History

On May 23, 2003, the plaintiff filed its complaint. On July 8, 2003, the defendant filed a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(1) for lack of subject-matter jurisdiction. The court now turns to that motion.

III. ANALYSIS

A. Legal Standard for a 12(b)(1) Motion to Dismiss

Federal courts are courts of limited jurisdiction and the law presumes that "a cause lies outside this limited jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994); *St. Paul Mercury Indem. Co. v. Red Cab Co.*, 303 U.S. 283, 288-89 (1938). Because "subject-matter jurisdiction is an 'Art. III as well as a statutory requirement[,] no action of the parties can confer subject-matter jurisdiction upon a federal court.'" *Akinseye v. District of Columbia*, 339 F.3d 970, 971 (D.C. Cir. 2003) (quoting *Ins. Corp. of Ir., Ltd. v. Compagnie des Bauxite de Guinea*, 456 U.S. 694, 702 (1982)). On a motion to dismiss for lack of subject-matter jurisdiction pursuant to Rule 12(b)(1), the plaintiff bears the burden of establishing that the court has subject-matter jurisdiction. *Evans v. B.F. Perkins Co.*, 166 F.3d 642, 647 (4th Cir. 1999); *Rasul v. Bush*, 215 F. Supp. 2d 55, 61 (D.D.C. 2002) (citing *McNutt v. Gen. Motors Acceptance Corp.*, 298 U.S. 178, 182-83 (1936)). The court may dismiss a complaint for lack of subject-matter jurisdiction only if "'it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.'" *Empagran S.A. v. F. Hoffman-Laroche,*

[1] The court does not suggest that this is an impermissible motive for the plaintiff's suit.

Ltd., 315 F.3d 338, 343 (D.C. Cir. 2003) (quoting *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957)).

Because subject-matter jurisdiction focuses on the court's power to hear the claim, however, the court must give the plaintiff's factual allegations closer scrutiny when resolving a Rule 12(b)(1) motion than would be required for a Rule 12(b)(6) motion for failure to state a claim. *Macharia v. United States*, 334 F.3d 61, 64, 69 (D.C. Cir. 2003); *Grand Lodge of Fraternal Order of Police v. Ashcroft*, 185 F. Supp. 2d 9, 13 (D.D.C. 2001). Moreover, the court is not limited to the allegations contained in the complaint. *Hohri v. United States*, 782 F.2d 227, 241 (D.C. Cir. 1986), *vacated on other grounds*, 482 U.S. 64 (1987). Instead, to determine whether it has jurisdiction over the claim, the court may consider materials outside the pleadings. *Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 197 (D.C. Cir. 1992).

B. Legal Standard for the Declaratory Judgment Act

Under the Declaratory Judgment Act, a court may declare the rights and other legal relations of any interested party where there exists an "actual controversy," defined as "a controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." 28 U.S.C. § 2201(a); *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941); *Mova Pharm.*, 140 F.3d at 1073. Even if such a controversy exists, however, a district court has broad discretion to withhold declaratory judgment. *Wilton v. Seven Falls Co.*, 515 U.S. 277, 287 (1995) (noting "the unique breadth of [a district court's] discretion to decline to enter a declaratory judgment"); *Jackson v. Culinary Sch. of Wash., Ltd.*, 59 F.3d 254, 256 (D.C. Cir. 1995) (stating that the Supreme Court "took great pains to emphasize the singular breadth of the district court's discretion to withhold declaratory judgment").

A plaintiff seeking declaratory judgment for patent infringement must satisfy a two-

pronged test to demonstrate that an actual controversy exists for purposes of subject-matter jurisdiction. *DuPont Merck Pharm. Co., v. Bristol-Meyers Squibb Co.*, 62 F.3d 1397, 1401 (Fed. Cir. 1995).[2] For an actual controversy to exist, "[t]here must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999) (internal quotation omitted); *accord Sigma-Tau Industrie Farmaceutiche Riunite, S.P.A. v. Lonza, Ltd.*, 36 F. Supp. 2d 26, 30 (D.D.C. 1999). Further, if there is no express charge of infringement, the plaintiff bears the burden of proof on the first element to show that, under the totality of the circumstances, the apprehension of suit was objectively reasonable. *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 888 (Fed. Cir. 1992); *Cylink v. Schnorr*, 939 F. Supp. 39, 41 (D.D.C. 1996).

C. The Court Grants the Defendant's Motion to Dismiss

As noted, the general rule for establishing an actual controversy in the patent infringement context requires a plaintiff to first show that it has a reasonable apprehension of suit. In the instant case, the plaintiff proposes an that an exception to that general rule. Specifically, the plaintiff suggests that the jurisdictional prerequisites for a declaratory judgment suit are met anytime an ANDA filer that files a paragraph IV certification is not sued by the pioneer patent holder within the 45-day window. Pl.'s Opp'n at 13. The Federal Circuit, however, has yet to recognize an exception to the general rule.

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[2] The Federal Circuit has jurisdiction over appeals of matters that arise under patent laws. 28 U.S.C. § 1295(a)(1).

The court recognizes that one member of the Federal Circuit has suggested that an exception to the general rule, as the plaintiff proposes, should exist. *Minnesota Mining & Mfg. Co. v. Barr Labs.*, 289 F.3d 775, 791 (Fed. Cir. 2002) (Gajarsa, J., concurring). This view is also shared by the D.C. Circuit who, even if it could be construed as dicta, interpret the statute as possibly allowing such an exception. *Mova Pharm.*, 140 F.3d at 1073 n.18. The *Mova* court stated that

> [t]he Federal Circuit has had no occasion to decide whether there is a "controversy of sufficient immediacy and reality" to support a declaratory judgment action, . . . when the plaintiff requires a judgment under section 355(j)(5)(B) in order to bring its product to market. It is possible that such a statutorily-created bottleneck, coupled with the statute's express reference to declaratory judgment actions as a means of relieving that bottleneck might suffice to allow a plaintiff to show the existence of a "case or controversy" without demonstrating an immediate risk of being sued.

Mova Pharm., 140 F.3d at 1073 n.18.

Thus, the court is faced with a dilemma. On the one hand, the court can look to non-binding precedent and defer to the plaintiff's suggestion. On the other hand, the court can simply not break rank with the established precedent, and follow the general rule. *See, e.g., Vanguard Research, Inc. v. Peat, Inc.*, 304 F.3d 1249, 1254 (Fed. Cir. 2002) (holding that reasonable apprehension is a prerequisite for jurisdiction for patent infringement suits brought under the Declaratory Judgment Act); *Sandt Tech., Ltd. v. Resco Metal Plastics Corp.*, 264 F.3d 1344, 1356 n.4 (Fed. Cir. 2001) (same); *Amana Refrigeration, Inc.*, 172 F.3d at 855 (same); *Dupont Merck Pharma.*, 62 F.3d at 1401 (same); *Arrowhead Indus. Water, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988) (same). In line with the court's limited jurisdiction and the presumption that a cause lies outside this limited jurisdiction, the court defers to the general rule and does not adopt the plaintiff's proposed exception. *Kokkonen*, 511 U.S. at 377.

The plaintiff next asserts that, under the totality of the circumstances, it has a reasonable apprehension that it will face an infringement suit for three reasons. Pl.'s Opp'n at 15-17. First, the plaintiff points out that the defendant has never expressly disclaimed an intention to sue it for patent infringement. *Id*. at 15. Second, the plaintiff argues that the defendant has a prior history of vigorous patent enforcement against companies that seek to market generic versions of its brand-name drugs. *Id*. at 16. Finally, the plaintiff notes that the defendant has previously engaged in litigation against the plaintiff. *Id*.

To begin with, the court recognizes that none of the plaintiff's three stated reasons creates a reasonable apprehension in and of itself. *See, e.g., B.P. Chems. Ltd v. Union Carbide Corp.*, 4 F.3d 975, 980 (Fed. Cir. 1993) (stating that "[a]lthough a patentee's refusal to give assurances that it will not enforce its patent is relevant to the determination, this factor is not dispositive) (internal citation omitted); *Int'l Harvester, Co. v. Deere, Co.*, 623 F.2d 1207, 1212 (7th Cir. 1980) (concluding that the plaintiff did not establish a reasonable apprehension of suit even when other litigation was pending between the two parties); *Premo Pharm. Labs. v. Pfizer Pharms., Inc.*, 465 F. Supp. 1281, 1283-84 (S.D.N.Y. 1979) (holding that a history of litigiousness by the defendant does not, by itself, support a reasonable apprehension of suit). Of course, whether the totality of the circumstances, as opposed to each fact individually, causes a reasonable apprehension of suit is a closer call.

In examining cases that apply the totality of the circumstances test to determine reasonable apprehension, a common denominator appears to be the analysis of some form of

communication about the patent at issue.[3] In some cases, the court focuses on the direct communication between the plaintiff and the defendant about the patent to find that a reasonable apprehension of suit exists. *See, e.g., Morphosys A.G. v. Cambridge Antibody Ltd.*, 62 F. Supp. 2d 100, 101-02 (D.D.C. 1999) (concluding that the defendant's fax of a press release to the plaintiff announcing the issuance of a U.S. patent covering the technology at issue constituted a "veiled threat" supporting the plaintiff's reasonable apprehension of a suit); *cf. Mallinckrodt Medical, Inc. v. Sonus Pharms., Inc.*, 989 F. Supp. 265, 269-70 (D.D.C. 1998) (concluding that the plaintiff did not have a reasonable apprehension of suit even though the defendant sent the plaintiff a letter enclosing a copy of its patent and did not expressly disclaim an intent to sue). In other cases, the court focuses on the communication between the defendant and a third-party to determine that a reasonable apprehension of suit exists. *See, e.g., Sigma-Tau*, 36 F. Supp. 2d at 30 (finding reasonable apprehension of a suit where the defendant sent a letter to the plaintiff's customer advising that the defendant's act of selling the product at issue "actively induces others to infringe [the defendant's patent]" and that the defendant would "take all necessary steps to enforce its rights"); *cf. Bonterra America, Inc. v. Bestman*, 907 F. Supp. 4, 7-8 (D.D.C. 1995) (finding no reasonable apprehension of suit despite the defendant's letter to the plaintiff offering a non-exclusive license arrangement, statement to a third-party that the third-party would be violating the defendant's patent if it continued to sell the plaintiff's product and directing the third-party to seek the advice of counsel to answer questions about the patent).

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[3] The court recognizes that the Federal Circuit has stated that "[i]f the circumstances warrant, a reasonable apprehension may be found in the absence of *any* communication from defendant to plaintiff.." *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731 (Fed. Cir. 1988). The *Arrowhead* court, however, did not specify the circumstances that would allow a reasonable apprehension to exist in the absence of any communications from the defendant to the plaintiff.

In the instant case, there have been no communications between the plaintiff and defendant, either direct or indirect, regarding the '450 patent. Rather, the defendant has simply stood silent. The plaintiff has not alleged that the defendant has asserted to the plaintiff that the plaintiff's product is in violation of the '450 patent. *See generally* Compl.; Pl.'s Opp'n. The plaintiff has not alleged that the defendant has conveyed to the plaintiff either expressly or implicitly that it intends to sue the plaintiff for infringement of the '450 patent. *Id*. The plaintiff has not alleged that the defendant has suggested to a third-party that it will sue the plaintiff for infringement of the '450 patent. *Id*. In fact, the plaintiff has not alleged that there have been any communications whatsoever from the defendant to the plaintiff with regard to the '450 patent. *Id*. In sum, the plaintiff's "purely subjective apprehension of an infringement suit is insufficient to satisfy the actual controversy requirement." *Indium Corp., v. Semi-Alloys, Inc.*, 781 F.2d 879, 883 (Fed. Cir. 1985). Accordingly, the court concludes that, under the totality of the circumstances, the plaintiff does not have a reasonable apprehension that it will face a patent infringement suit. *Shell Oil*, 907 F.2d at 888. Thus, an actual controversy does not exist and the court grants the defendant's motion to dismiss. *Mova Pharm.*, 140 F.3d at 1073.

IV. CONCLUSION

For the foregoing reasons, the court grants the defendant's motion to dismiss. An order consistent with this Memorandum Opinion is separately and contemporaneously issued this ____ day of March, 2004.

RICARDO M. URBINA
United States District Judge